

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13187



4 - ER URGENT

**000001**

**EMERGENCY DEPARTMENT REPORT**

**PATIENT NAME:** [REDACTED]

**ROOM #:** [REDACTED]

**MEDICAL RECORD #:** [REDACTED]

**DC MED RECORD #:** [REDACTED]

**DATE:** 09/12/98

**COPY TO:** [REDACTED] MD  
[REDACTED] MD

**EMERGENCY PHYSICIAN:** [REDACTED] MD

**CHIEF COMPLAINT:** Abdominal pain

**HISTORY OF PRESENT ILLNESS:** 56-year-old woman around noon developed pain across her whole upper abdomen like a band around her upper abdomen. She felt bloated last night. The pain is constant although intermittently it waxes and wanes.

**REVIEW OF SYSTEMS:** No chills, fever, weight loss, dysphagia, chest pain, shortness of breath, history of ASCVD or lung disease. Some nausea, no vomiting, constipation, or diarrhea. Much belching. No history of biliary tract disease or ulcers. No prior history of pancreatitis. She denies urinary symptoms. No vaginal drainage, discharge, or bleeding. She is postmenopausal.

**PAST MEDICAL HISTORY:** On Premarin and Minocycline for rosacea. Allergic to contrast, gets hives.

**SOCIAL HISTORY:** Lives locally. She does not drink significant alcohol.

**PHYSICAL EXAMINATION:** T 36. BP 147/98. P 82. R 20. Pleasant but pale and diaphoretic middle-aged female NAD. She looks uncomfortable.

**HEENT:** Unremarkable other than mild chronic rash.

**NECK:** Supple without adenopathy.

**RESPIRATORY:** Breath sounds are clear throughout without crackles, rhonchi, or wheeze. Breathing nonlabored. No accessory muscle use.

**CARDIOVASCULAR:** Regular rate. Normal S1 and S2 without gallop or murmur.

**ABDOMEN:** Soft with moderate pain across her upper abdomen. No guarding, rigidity, or rebound. Bowel sounds are normal. No mass or organomegaly is perceived.

**EXTREMITIES:** Clammy and cool.

**CLINICAL COURSE:** She was given Toradol IV for pain 30 mg. Ultrasound revealed a normal gallbladder and common bile duct. Hemoglobin 16.3. White count 13,300. Amylase is markedly elevated at 1296. Liver profile otherwise normal with the exception of AST of 60.

**000002**

**EMERGENCY DEPARTMENT REPORT**  
**ORIGINAL**

Memo Date: January 11, 1999  
Subject: F/U Adverse Report [REDACTED]  
To: Dorothy L. Olson, ASCSO  
From: Thomas S. Donaldson, CSO  
Exhibit No: page of

medWatch Report #13187  
Follow-Up Adverse Report  
Thomas S. Donaldson 01-11-99  
Exhibit: 3 page 6 of 48

**EMERGENCY DEPARTMENT REPORT - Page 2**

**PATIENT NAME:** [REDACTED]

**MEDICAL RECORD #:** [REDACTED]

**IMPRESSION:** Pancreatitis, etiology unclear

**PLAN:** Admitted to a medical bed. Await Dr. [REDACTED] call. She will be kept NPO, placed on IV fluid, and allowed pain medication.

Dictated and Authenticated by:

cc: [REDACTED] MD  
[REDACTED] MD

DD: 09/12/98

TD: 09/12/98 8:27 [REDACTED]

medWatch Report #13187  
Follow-Up Adverse Report [Signature]  
Thomas S. Donaldson 01-11-99  
Exhibit: 3 page 7 of 48

Memo Date: January 11, 1999  
Subject: F/U Adverse Report/Duluth, MN  
To: Dorothy L. Olson, ASCO  
From: Thomas S. Donaldson, GSO TSO [Signature]  
Exhibit No: [ ] page of

**EMERGENCY DEPARTMENT REPORT**  
**ORIGINAL**

**000003**